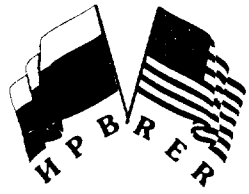

РОССИЙСКАЯ ФЕДЕРАЦИЯ -
СОЕДИНЕННЫЕ ШТАТЫ АМЕРИКИ

RUSSIAN FEDERATION -
UNITED STATES OF AMERICA

МЧС

DOE

ИСПОЛНИТЕЛЬНЫЙ КОМИТЕТ ОКК ИРВ

EXECUTIVE COMMITTEE JCC RER

Третье
Совещание

Third
Meeting

14–17 июля 1995 г.
С.-Петербург

July 14-17, 1995
St. Petersburg

(3) In addition to those set forth under the foregoing two items, a person who was at the time of or after the atomic bombing in such circumstances as would expose him to the effects of A-bomb radiation.

(4) A person who was an in-utero baby of an individual falling under any of the preceding three items at the time the condition stipulated therein was applicable to the individual.

Chapter 2 Health Management

(A-bomb Survivors Health Handbook)

Article 3. A person who wishes to receive an A-bomb Survivors Health Handbook must apply to the governor of the prefecture (the mayor, when residence is in Hiroshima or Nagasaki City. The same shall apply hereinafter) in which he resides (present address, when he has no residence. The same shall apply hereinafter)

2. The prefectural governor shall, when he on studying the application of the foregoing clause deems that the applicant falls under one of the items of the foregoing article, issue an A-bomb Survivors Health Handbook to the applicant.

3. The necessary provisions for the A-bomb Survivors Health Handbook shall be set forth in the Government Ordinance

(Record of Health Examination)

Article 5. The prefectural governor shall, when he has conducted health examination under the provision of the foregoing article, prepare a record of the health examination and preserve it for the period prescribed in the Welfare Ministry Ordinance.

(Guidance)

Article 6. The prefectural governor shall, when he deems it necessary as a result of the health examination conducted under the provision of Article 4 (Health Examination), provide necessary guidance to the individual who received the health examination.

the entire project. These plans should briefly describe the: background; specific aims; scientific rationale for conducting the project; research design and the procedures to be used to accomplish the specific aims of the project; tentative timetable for the project; specific tasks to be carried out by each side during the pilot project; resources needed to carry out the project; and collaborators from both sides. In addition, the pilot project plans should also describe how a determination will be made as to whether a full-scale project is appropriate and the type of longer-term research envisioned if the pilot project is successful. These pilot projects shall be limited in scope and have a specific end-point. The written project plan should be an abbreviated version of a full proposal for a long-term project described in Section III below. Plans for short-term or pilot projects involving contact with human subjects must be reviewed and approved by the appropriate institutional review boards in both countries. No pilot project shall last beyond the timetable specified in the pilot project plan, unless, after close scrutiny, the JCCRER determines that additional pilot work is deemed necessary before making a decision on launching a long-term project.

B. Acceptance Process

Proposals for pilot studies pursuant to long-term projects, or proposals for short-term cooperative projects, must be submitted through the Executive Committee to the appropriate Scientific Review Group (SRG) for review and evaluation. The SRG will review the proposals, evaluate the potential scientific merit of the project, and make recommendations to the EC. Each year the recommendations of the SRG shall be presented by the EC to the JCCRER at its annual meeting for acceptance.

During the year following the first meeting of the JCCRER, the EC will facilitate the initiation of four of five pilot projects that are most critical to the implementation of the highest priority long-term studies. Continuation of these projects shall be subject to review and acceptance by the JCCRER at the end of the first year. The EC may also initiate a few limited scope projects during the first year.

III. Long-Term Projects

A. Development of Research Plan

Research plans shall be developed jointly by the PRT of scientists from the United States and the Russian Federation who are involved in the actual conduct of a project. The research plan should answer the following questions: (1) What do you intend to do? (2) Why is the work important? (3) What has already been done? (4) How are your going to do the work? Each research plan should have the following sections:

1. **Abstract** - This should be a one-page summary of the specific aims, background and significance, and research design and methods.

2. **Specific Aims** - State the long-term objectives and describe what the specific research in this plan is intended to accomplish and the hypotheses to be tested.

3. **Background and Significance** - Discuss the background of the present plan, evaluate existing knowledge, present scientific rationale for conducting the study, and specifically identify the gaps which the project is intended to fill. State the importance of the research described in the plan and how it fits into the program of cooperation approved by the JCCRER.

4. **Preliminary Studies** - Discuss results of pilot or feasibility work that was conducted in preparation for the long-term project, and provide evidence that this plan is feasible.

5. **Research Design and Methods** - Describe the research design and the procedures to be used to accomplish the specific aims of the project. Include the specific methods by which the data will be collected, analyzed, and interpreted. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. Provide a tentative timetable for the investigation. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

6. **Quality Assurance/Quality Control** - Discuss specific procedures for ensuring the accuracy and quality of the data to be collected.

7. **Collaborators/Collaborating Institutions** - List the names and affiliations of collaborators for both countries, including one Principal Co-Investigator from each country. This is the team of principal scientists (PRT) conducting the work on the project. The specific roles of the collaborators in the conduct of the project should be clearly defined, along with a list of tasks to be conducted by the United States and the Russian Federation sides. Include a discussion of the existing resources to be made available for use by the study team.

8. **Human Subjects Considerations** - Describe the subjects who will be included in the investigation and how they will be enrolled. Identify the specific procedures, tests, and/or issues involving humans, and describe possible risks, ethical issues, and/or side effects for each. When the study involves contact with the subjects, describe in detail how informed consent

2. When it is not possible or it is deemed unsuitable to follow the policy of examination and treatment and remuneration thereof as prescribed in the foregoing clause, the policy for examination and treatment and remuneration thereof shall be decided by the Welfare Minister upon consulting the A-bomb Survivors Medical Treatment Council.

(Review and Disbursement of Esamination and Treatment Remuneration)

Article 12. The Welfare Minister can review at any time the contents of the examination and treatment provided and the remuneration request thereof made by a designated medical institution and determine the amount of remuneration which a designated medical institution can request under the provision of the preceding article.

2. A designated medical institution must accept the decision made by the Welfare Minister under the foregoing clause.

3. The Welfare Minister must, when determining under the provision of Clause 1 the amount of examination and treatment remuneration which a designated medical institution can request, consult the Deliberation Committee established under the Social Insurance Examination and Treatment Remuneration Disbursement Fund Law (Law No. 129, 1948).

4. The Government can entrust the clerical work of disbursement of examination and treatment remuneration to designated medical institutions to the Social Insurance Examination and Treatment Remuneration Disbursement Fund.

5. Appeals under Administrative Appeals Review Law (Law No. 169, 1962) cannot be made on decisions regarding amount of examination and treatment remuneration prescribed under Clause 1.

(Request for Reports and Inspection)

Article 13. The Welfare Minister can, when necessary for the inspection prescribed under Clause 1 of the foregoing article, request the administrator of a designated medical institution to present necessary reports or, with the consent of the administrator of the designated medical institution, have competent officials personally inspect the examination and treatment records and other books and documents of the designated medical institution.

IV. Reporting of Progress and Results

Each PRT shall provide written progress reports to the Executive Committee co-chairs and the appropriate SRG co-chairs at least every four months. These reports shall contain the following information: description of progress made during the four months, changes in procedures, equipment and supplies purchases, exchange trips taken, corrective actions taken as a result of quality assurance procedures, and milestones reached. The EC will report SRG recommendations and PRT progress to the JCCRER at each annual meeting.

For limited-scope projects, a final report which includes a description of project objectives, methods, results and final recommendations and/or a protocol for future work should be submitted to the EC and the appropriate SRG within 3 months of completion of the project.

All long-term projects shall be designed to produce information which is suitable for publication in the peer-reviewed scientific literature during the course of the project or on its completion. Manuscripts will be jointly prepared and submitted for publication by members of the PRT responsible for the project. Publication of interim and/or final results of any project shall be fully coordinated within the appropriate PRT. In addition, each PRT shall develop and implement a public involvement plan designed to facilitate communication concerning the nature of the project and the project research results to the public at large.

Results will be released when the PRT co-chairs agree that such publication or release is appropriate. The PRT co-chairs together with the other PRT members involved in the conduct of the project will make the final decision on the content of their publications. However, if unresolved differences of a scientific nature arise between PRT members, then the appropriate SRG may act to resolve those differences.

Prior to the publication of results, the PRT co-chairs from each side will inform the EC of their plan for communicating these results to the scientific community and the public. The EC and the JCCRER may advise the PRT on mechanisms and plans for release of results. Public release of research results should occur within one year of completing data analysis.

Publication of results and exchange of information between members of PRT shall be carried out in accordance with the Annex on Intellectual Property to the Agreement between the Government of the United States of American and the Government of the Russian Federation on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment signed on January 14, 1994.

V. Data Access and Sharing

During the conduct of any cooperative pilot, short-term, or long-term project, members of the PRT on both sides will have access to all data gathered for the project or to be used in analysis of results. After the PRT has had sufficient opportunity to prepare final reports, data used in the final analyses should be available to inquiring scientists. Procedures for allowing access to data collected for each pilot, short-term, and long-term project should be developed by the PRT and reviewed by the EC. Strict procedures should be applied to ensure that privacy of individual study subjects is protected. Existing public use databases might be used as a models or as vehicles for making these data available to the scientific community. A mechanism and timetable for data access and sharing should be developed, allowing reasonable time for the Project Research Team (PRT) to publish study results. In addition, an effort should be made to communicate the research results to the public at large.

VI. Separately Funded Research Projects

It is recognized that some areas of potential mutual scientific interest exist where limited or small-scale studies could have the potential to contribute significant new scientific knowledge on radiation effects. These studies are not initiated or proposed to necessarily conform to the JCCRER process applicable to other short-term studies. These studies should be fully coordinated with the JCCRER activities to avoid unnecessary duplication of efforts. Recognition of the cooperative relationship between separately funded research and that performed under the JCCRER cooperative research program is essential to a fully successful research program.

Projects of any size and duration, which pre-date the signature of the Agreement and are separately funded by participating agencies should also be fully coordinated with the EC during the year following the first JCCRER meeting.

Both pre-existing and new projects that are separately funded research projects may be offered for consideration and joint funding under the JCCRER cooperative research program at the sponsoring agency's option. In such cases, submitted studies should demonstrate conformity to the JCCRER review guidelines as outlined in the above Sections, prior to adoption by the JCCRER.

СОГЛАШЕНИЕ

между Правительством Российской Федерации

и

Правительством Соединенных Штатов Америки

о

СОТРУДНИЧЕСТВЕ В ОБЛАСТИ ИЗУЧЕНИЯ РАДИАЦИОННЫХ ВОЗДЕЙСТВИЙ С ЦЕЛЬЮ МИНИМИЗАЦИИ ВЛИЯНИЯ ПОСЛЕДСТВИЙ РАДИОАКТИВНОГО ЗАГРЯЗНЕНИЯ НА ЗДОРОВЬЕ ЧЕЛОВЕКА И ОКРУЖАЮЩУЮ СРЕДУ

AGREEMENT

between the Government of the United States of America

and

the Government of the Russian Federation

on

COOPERATION IN RESEARCH ON RADIATION EFFECTS FOR THE PURPOSE OF MINIMIZATION OF CONSEQUENCES OF RADIOACTIVE CONTAMINATION ON HEALTH AND THE ENVIROMENT

Direction 2

RESEARCHES ON MEDICAL CONSEQUENCES OF PERSONNEL EXPOSURE TO RADIATION

PROJECT 2.3

Deterministic effects of Occupational Exposure to Radiation

Moscow

1995

Clause 3 (Order to Those Providing Medical Treatment to Submit Records and Documents at Time of Payment of Medical Treatment Expenses) when necessary for payment of medical treatment expenses for general sickness.

(Restriction on Payment of Medical Expenses for General Sickness)

Article 14. Paragraph 6. When a special A-bomb survivor becomes injured or sick by his own willfull criminal act or by design, medical treatment for general sickness shall not be paid for such injury or sickness.

Article 14. Paragraph 7. When a special A-bomb survivor becomes injured or sick due to fighting, intoxication or gross misconduct, payment of general sickness medical treatment expenses for such injury or sickness can be wholly or partly withheld. The same shall apply when a special A-bomb survivor through gross negligence on his part becomes injured or sick or without justifiable reason fails to follow the instructions concerning treatment.

(Medical Treatment Allowance)

Article 14. Paragraph 8. The prefectural governor can under the provision of the Government Ordinance pay to a survivor for the period that he receives medical treatment benefits under the provision of Article 7, Clause 1 (Medical Treatment Benefits) medical treatment allowance in an amount not to exceed 2,000 yen monthly.

Chapter 4. A-bomb Survivors Medical Treatment Council

(Establishment and Authority)

Article 15. The A-bomb Survivors Medical Treatment Council (hereinafter referred to as the Council) shall be established in the Welfare Ministry as an auxiliary organ of the ministry to provide advice at the request of the Minister and to investigate and review important matters concerning medical treatment of A-bomb survivors.

2. The Coucil can present to the ministers concerned its opinion on matters concerning medical treatment of A-bomb survivors.

(Membership)

Article 16. The Council shall be organized of 20 members or less.

2. The members shall be appointed by the Welfare Minister from among men of learning and experience and from among the staff of the administrative organs concerned.

PROJECT 2.3

DETERMINISTIC EFFECTS OF OCCUPATIONAL EXPOSURE TO RADIATION

PHASE 1: **Feasibility Study**

PRINCIPAL INVESTIGATORS

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1. SUMMARY

This Phase I short-term feasibility study between the Russian Federation (RF) and the United States (US) is divided into two major areas, clinical aspects; and dosimetry and risk assessment modelling. It will last 12 to 18 months and relates to the evaluation of deterministic (nonstochastic) clinical radiation effects in a unique population, the Russian Federation MAYAK PA workers chronically and/or acutely exposed to internal and/or external radiation.

The feasibility study focuses on the clinical, hematological, and cytogenetic effects resulting from doses that can lead to deterministic effects. The MAYAK PA data will be critically reviews and assessed for availability, suitability, and adequacy. A parallel investigation will be conducted into external and internal dosimetry. Computer software will be developed during phase I to test a prognostic model for hematopoietic effects (NUREG/CR-4214). Pending the successful completion of the feasibility phase, a full proposal for continued collaborative rersearch encompassing the whole MAYAK PA worker population will be submitted to the Executive Committee.

2. BACKGROUND

During the past 50 years, defense-related activities in the Russian Federation and in the United States has resulted in occupational radiation exposures of defense nuclear workers as well as population exposures. For many years, most of the data related to such exposures were classified. Recently, information became available about activities of the first Russian nuclear facility, MAYAK PA, in the South Urals (Ilyin, 1995). Several thousands of workers were exposed to relatively high levels of external gamma radiation and, in many cases, to internal alpha radiation from inhaled plutonium as well. The cumulated doses over 1 to 7 years (1948–1953) were as high as 1–10 Gy. A number of these workers developed health impairments that are considered to be forms of radiation sickness. More than 1800 cases of occupational diseases were diagnosed in 1960 and chronic radiation sickness was a major contributor to the total. This syndrome was described by A.K. Guskova and G.D. Baisogolov (1971). Also included among early deterministic effects were cases of acute radiation syndromes, local radiation injuries, and cataracts as well as pulmonary pneumosclerosis following large plutonium inhalations (Okladnikova et al., 1992, 1994a,b,c and 1995).

Systematic medical observations were carried out as part of the radiation protection program that began with the start-up of MAYAK PA. For 45 years these unique data were collected, now allowing the study of a wide range of deterministic effects, including those involving the hemopoietic, immune, nervous, cardiovascular, visual, and cytogenetic systems as well as the key organs op plutonium deposition, i.e. liver, lungs, and skeleton.

These clinical and dosimetric data provide the basis for ascertaining the dose thresholds and dose-response relationships for the deterministic effects of prolonged radiation exposure, and permit comparisons to the same aspects od acute effects observed in other memebers of the same cohorts. These data will facilitate the development and testing of prognostic models for predicting the consequences of prolonged and intermittent radiation exposures ranging from sublethal to subclinical. This would obviate the need to rely entirely on extrapolations from the clinical outcomes of single high dose rate exposures such as the experiences of Atomic Bomb survivors or occupationally exposed ARS patients.

3. RATIONALE FOR THE PROJECT

Most of our current knowledge about nonstochastic (deterministic) radiobiological effects of ionizing radiation has been derived (1) from studies of populations exposed briefly at high rates to gamma rays (or gamma rays and neutrons) from atomic bombs; (2) from data about medical complications arising

from fractionated, localized photon exposure during radiation therapy for cancer; or (3) studies of external or internal exposure of laboratory animals to high- and/or low-LET radiations. There are few published data about deterministic effects in humans caused by inhalation of radioactive materials, or by irradiation from combined external gamma and internal alpha, beta, and gamma sources acutely and/or chronically — situations that might occur in nuclear accidents. The MAYAK PA data provide an opportunity to test existing models for deterministic effects of chronic exposure to ionizing radiation (external or external plus internal) and to develop new models for key effects of prolonged radiation exposure, such as chronic radiation sickness (CRS) and plutonium pneumosclerosis.

4. SPECIFIC AIMS FOR PHASE I

The major aim of the proposed pilot project is to determine the feasibility of a collaborative health study of the entire MAYAK PA worker population for deterministic effects of their occupational radiation exposure. Because Phase I effects are limited in time, they will have to focus primarily on MAYAK PA workers employed at any time in the period from 1948 to 1953.

Specific aims for the Phase I feasibility study are:

A. To review the existing MAYAK PA data bases for quality, completeness, and suitability of dosimetric, clinical, hematological, and cytogenetic data.

B. To determine the feasibility of defining a study cohort drawn from the 1948 to 1953 worker population based on availability of both individual dose history and clinical effects data.

C. To develop computer software that will allow testing of a health effects model for hematopoietic effects. The program will use time-dependent organ dose rates.

D. To study materials provided by the RF scientists concerning the diagnostic criteria and techniques defining the neurovascular form of CRS after external exposure with the goal of developing a cooperative investigation in this area.

5. RESEARCH DESIGN AND PROCEDURES

A. Perform an on-site visit by US team to Chelyabinsk-65 (Ozyorsk) to attain familiarity with available data and materials and to participate in developing the feasibility study.

B. Jointly make a detailed review of fundamental components of the clinical data of the selected group of MAYAK PA workers (1948–1953 employees).

C. Reach agreement on procedures to select the primary clinical data for insertion into a joinly accessible computerized database for the study of human deterministic radiation effects.

D. Perform an on-site visit by RF team to Pittsurgh to participate in the development of a summary report.

6. SPECIFIC TASKS TO BE CARRIED OUT

A. Develop agreement on operational meaning of the scientific and medical terminology to be employed, including quantitative classifications of clinical signs, symptoms, and nosologic forms. (US to initiate dialogue.)

B. Prepare a mutually agreed upon coding plan for the extraction and summarization of relevant clinical, hematopoietic, cytogenetic, and dosimetric data from existing primary records for the group of MAYAK PA workers wmploed between 1948 and 1953. (US to propose initial coding plan for discussion.)

C. Assess need for and agree upon necessary computer hardware and software to be used by RF in Phase I feasibility work and retained for further work. Scientific attention is to be given to the need for compatibility between RF and US hardware and software to assure collaborative use of the feasibility data base. (RF and US to assess needs collaboratively.)

D. Implement the coding plan for a randomly selected stratified feasibility sample of MAYAK PA workers (see attached plan) and create a computerized database to contain the coded information. (US to propose the sampling plan including randomization procedure, and, following mutual agreement, work to be carried out by RF in collaboration with US.)

E. Compare randomly selected elements of the coded information in the computerized database to the contents of the primary records in order to assess the reliability and completeness of the coding and extraction procedures. (US to carry out in collaboration with RF.)

F. Develop a mutually agreed upon plan for analyzing the computerized feasibility sample of MAYAK workers and carry out the analyses required to assess the validity of the information in the database and its suitability for use in a larger study (US to initiate dialogue, RF to perform.)

G. Develop a computer program that will allow testing of the health effects model for hematopoietic death. The program should allow for the use of a time dependent organ dose rate. (US to perform.)

H. Study materials concerning diagnostic criteria and techniques for defining the neurovascular form of CRS and identify appropriate US scientists to participate in the development of a comparative investigation in this area., (RF to initiate implementation.)

MINIMUM SAMPLING PLAN FOR THE NONSTOCHASTIC EFFECTS (2.3) PHASE I FEASIBILITY STUDY

WORKER CATEGORY	ESTIMATED TOTAL SIZE	PROPOSED SAMPLE SIZE
A. NO KNOWN OCCUPATIONAL CONDITIONS*	6366	100
Male	4170 (65.5%)	50
Females	2196 (34.5%)	50
B. CHRONIC RADIATION DISEASE**	1528	100
Local Injuries	188	19
Other	1340	81
C. ACUTE RADIATION SYNDROME**	41	14
High Severity	13	5
Lower Severity	24	5
Deaths	4	4
D. PU PNEUMOSCLEROSIS**	120	12
Pure	66	7
Combined	54	5
TOTALS	8055	226

* category and size estimated from Ilyin, 1995

**category and size estimated from Okladnikova, 1994a

7. TENTATIVE TIME TABLE

TASK	MONTH
Preparatory work for Phase I including	1-3
– agreement on terminology	
– development of coding plan for primary data	
– agreement on plan of feasibility data analysis	
Duscuss, Jointly Decide Upon (per Pg.6, Sec. 6,C.), Deliver, Set-up and Test Computer Equipment	4
Database Programming	5
Extraction of Primary Data	6-13
Initial QA/QC	6
Final QA/QC	13
Feasibility Data Analysis	14-15
Develop Model Testing	1-9
Review Neurovascular CRS Information	5-12
Prepare Summary and Long-Term Plan	16-18

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СОГЛАШЕНИЕ

между Правительством Российской Федерации

и

Правительством Соединенных Штатов Америки

о

СОТРУДНИЧЕСТВЕ В ОБЛАСТИ ИЗУЧЕНИЯ РАДИАЦИОННЫХ ВОЗДЕЙСТВИЙ С ЦЕЛЬЮ МИНИМИЗАЦИИ ВЛИЯНИЯ ПОСЛЕДСТВИЙ РАДИОАКТИВНОГО ЗАГРЯЗНЕНИЯ НА ЗДОРОВЬЕ ЧЕЛОВЕКА И ОКРУЖАЮЩУЮ СРЕДУ

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Direction 3

INFORMATION TECHNOLOGIES IN RESEARCHES ON RADIATION EFFECTS AND DECISION-MAKING SUPPORT

PROJECT 3.2

Assistance on Emergency Planning and Response based on Russian and U.S. Experience

Moscow

1995

Project 3.2

Title: **Assistance on Emergency Planning and Response based on Russian and U.S. Experience**

Summary: The purpose of the first-year's collaborative project is to develop a set of guidelines, checklists, and reference documentation (field manual) that provides practical insights based on U.S. and Russian experience and that should be considered and taken into account while responding to a radiological emergency.

Project 3.2A

Product: A "Field Manual" for use when responding to large radiological accidents. It will contain guidelines, checklists, and reference data that provides practical insights based on U.S. and Russian experience. This may include guidance on:

- Monitoring and decontamination of larger geographic regions.
- Personnel monitoring and decontamination.
- Medical treatment and support of large numbers exposed people (public).
- Radioprotective strategies for emergency responders.
- Public information concerning the risks from contamination.

Following development of the manual, training materials and a course for state responders may be developed.

Strategy: Convene a group of 5-7 experts from each country with first hand experience in dealing with contaminating accidents or developing procedures for responding to such accidents. This group will draft the manual at two workshops.

Milestones:

Complete the outline of the practical guidance concerning the variable nature of deposition of radioactive material, the problems of assessing (monitoring) actual local dose levels and of associating these to larger geographic regions for projecting early and intermediate phase doses for deposition and ingestion for the population.

July 1995 - Executive Committee (EC) identifies 5-7 expert participants from each country. EC discusses and approves final topics for the Field Manual.

July 1995 - U.S. Co-chair assigns topics to U.S. participants to prepare preliminary (0) draft of sections.

September 1995 - Distribute preliminary draft sections by U.S. participants to all U.S. and Russian participants for review.

October 1995 - Russian participants provide comments on preliminary (0) draft and sections prepared by the U.S. participants and provide input on topics not covered.

November 1995 - Conduct 3-day workshop in United States to discuss draft sections, exchange information and produce collaboratively the first draft of the manual.

January 1996 - Revise draft sections based on workshop and distribute to participants.

February 1996 - Submit comments on draft manual for preparation of final draft.

March 1996 - Conduct 3-day workshop in Russia to discuss final draft manual.

June 1996 - Technical edit of manual completed and commented on by participants.

September 1996 - Manual translated into Russian and published.

Budget: **Fiscal Year 1996**

$50,000 to conduct workshop in United States and compile first draft.
$50,000 to conduct workshop in Russian and complete final draft.
$10,000 to complete final edit and translate into Russian.

This assumes that 1) travel of U.S. participants will be paid for by their agencies, 2) the participating U.S. agencies will provide clerical support and editing, and 3) the participating U.S. agencies will publish the document at no cost.

Project 3.2B

Following the development of the manual, develop an outline of exercise scenario for a large radiation accident in which the manual can be tested. Identify the scenario materials for this exercise by September 1996.

All project final reports shall be submitted according to Section IV - Reporting of Progress and Results Guidelines for Conducting Scientific Research Projects under the Agreement of Cooperation in Research on Radiation Effects - Revised February 15, 1995.

Resources:

The Russian side will provide up to six senior investigators and scientists on a full-time basis. The American side will provide five to seven collaborating scientists and individual participation, in general, will not exceed 20 percent.

Approval:

The Executive Committee for the JCCRER has reviewed and approved the implementation of Project 3.2 in accordance with the milestones and resources stipulated above.

For the Russian Federation:

July 1995

For the United States:

July 1995

RADIOLOGICAL ACCIDENT RESPONSE FIELD MANUAL OUTLINE

Draft June 9, 1995, coordinated by Maria Pavlova

Purpose:

This Manual provides practical guidance on responding to severe radiological accidents. This is a compilation of the lessons learned by Russia and United States responders. This manual is an attempt to capture those insights that were learned by actually doing the various tasks associated with a response both action to take and to avoid. This Manual is not intended to provide guidance on how to perform detailed technical assessments such as calculating dose or determining if national standards (Intervention Levels or Protective Actions Guides) are exceeded. Guidance on performing these types of calculations are provided elsewhere and listed below.

Table of Contents

(This is a list of potential topics. The actual areas addressed by the manual will be limited to those areas where real life insights are provided.)

A. Organization and Logistics

1 – notification
2 – organization
3 – command and control
4 – decision making
5 – procedures
6 – training
7 – facilities
8 – communications
9 – supplies

B. Communicating with:

1 – decision makers
2 – public - with the goal of producing an informed and collaborative public that is involved in the decision making process
3 – media
4 – other responders
5 – elected officials
6 – NGOs
7 – other countries (point of contact for each country)
8 – international organizations
9 – regulatory officials
10 – uninvolved - those who think they have a role and do not.

C. Protective Actions

1 – communication to public
2 – decision making
3 – public notification
4 – access control
5 – evacuation, relocation
6 – sheltering
7 – thyroid blocking

8 – providing uncontaminated food, water, shelter
9 – food processing
10 – agricultural intervention (e.g., additional fertilizers)
11 – food interdiction
12 – special populations and facilities (e.g., hospitals, prisons)
13 – dealing with existing medical conditions

D. Emergency Workers and Medical Personnel

1 – control and direction
2 – instruction, communications
3 – instrumentation
4 – exposure control/dosimetry
5 – respiratory protection (e.g., use of gas masks)
6 – contamination control (e.g., personal protective equipment and clothing)

E. Medical

1 – organization
2 – procedures
3 – training
4 – facilities
5 – supplies
6 – health physics support
7 – clinical assessment
8 – radiation exposure assessment: biological assay
9 – thyroid dose
10 – whole body counting
11 – patient tracking
12 – triage
13 – treatment
14 – follow-up
15 – contaminated human remains burial
16 – waste disposal
17 – patient registry

F. Public Health Concerns

1 – public health surveillance
2 – communicable disease control
3 – long term follow up and data collection
4 – crisis counseling
5 – sanitation

G. Monitoring/Sampling

1 – procedures and strategies
2 – training
3 – instruments
4 – communications
5 – team control
6 – results analysis and display
7 – data control, logging, tracking
8 – laboratory analysis

9 – data analysis and display
10 – conduct in field in different weather and terrain
11 – gamma exposure rates
12 – very high gamma fields
13 – beta, alpha
14 – food
15 – milk
16 – water
17 – deposition
18 – vegetation/forage
19 – plume
20 – resuspension
21 – mobile laboratories
22 – fixed vs. mobile monitoring

H. Contamination Control and Decontamination

1 – people
2 – buildings
3 – vehicles
4 – roads..surfaces
5 – large areas
6 – instruments
7 – equipment
8 – water sources
9 – food
10 – waste disposal
11 – contaminated animals

I. Other

1 – communication means/systems
2 – exercises/training
3 – meteorological support
4 – source terms
5 – dose assessments (e.g., computer codes)

Reference/Source Documents/Existing Legislations

- Response Technical Manual, NUREG/BR-0150, US NRC, 1993 (revision due in fall), Based on US units and criteria it provides methods for: 1) assessing LWR accident conditions, 2) projecting dose based on LWR conditions, 3) projecting dose based on release rates and 4) assessing environmental data.
- International Response Technical Manual, Draft May, 1995, US NRC, Based on IAEA SS-109 and using SI units it provides methods for: 1) assessing LWR (PWR, BWR and VVER) accident conditions, 2) projecting dose based on LWR conditions, 3) projecting dose based on release rates and 4) assessing environmental data.
- FRMAC Assessment Manual, Scheduled to be published soon, DOE... , Based on US Units and criteria provides methods for assessing environmental data.
- Nuclear Weapons Accident Response Procedures Manual, Dod 5100.52-M, September 1990. This is a fairly complete description of Dod and other Federal Agency response to a weapons accident. Local and state governmental responsibilities are also described.

- FEMA REP 14
- FEMA REP 15

Glossary/International Dictionary

Project 3.2

List of US Candidates for Workgroup on Field Manual

Environmental Monitoring and Assessment

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Joint Coordinating Committee for Civilian Nuclear Reactor Safety (JCCCNRS); Working Group 7 (Health and Environmental Consequences)

Brief Status of Current JCCCNRS Working Group 7 Activities with Russian Federation Involvement; June 30, 1995

JCCCNRS Working Group 7 Leader for the United States is Dr. Harry Pettengill

JCCCNRS Working Group 7 Leader for the Russian Federation is Dr. Anatoly Tsyb

Last JCCCNRS Meeting was Held in Moscow, Russian Federation, May 16-17, 1994 (Record of Meeting Available)

I. Project Title - Bryansk Feasibility Study:

- In 1992-3, DOE Reviewed Pilot Proposal by the Fred Hutchinson Cancer Research Center (FHCRC) in Seattle, Washington;
- FHCRC Received DOE Grant for Start-up Phase from January 21, 1994 to March 20, 1995, to Develop Proposal for Short-Term Feasibility Study;
- FHCRC Submitted to DOE Proposal for a 2-Year Feasibility Study in Bryansk Region Related to the Chernobyl Accident;
- U.S. Office of Naval Research (ONR) Recently Funded a Separate Fred Hutchinson Cancer Research Center Proposal, with Activities Complementary to Bryansk Feasibility Proposal Submitted to DOE (ONR Proposal Emphasizes Russian Field Work);
- Bryansk Feasibility Study Proposal Now in DOE Peer Review Process; Evaluation Expected Within 6 Months;
- Concept of Bryansk Feasibility Study Proposal is to:
  - Identify and Establish Cohorts in Bryansk Region Exposed to Chernobyl Radiation;
  - Develop and Evaluate Methods for Estimating Doses and Ascertaining and Verifying Health Status for Cohorts; - Establish Capability for Preservation and Storage of Genetic Specimens;
  - Evaluate Capability for Assembling and Analyzing Dosimetric and Health Status Data for Epidemiologic Study

II. Other Working Group 7 Activities with Russian Federation Involvement - Childhood Thyroid Disease (Cancer) Study in Belarus:

- Joint Research Protocol Signed in May 1994;
- For the U.S. Side: National Cancer Institute (NCI) Leading Protocol Implementation; Lawrence Livermore National Laboratory Procuring Equipment/Supplies and Assisting on Dosimetry; U.S. Side Supported by DOE, NCI, and Nuclear Regulatory Commission;
- Radiation Dosimetry Activities for this Study in Belarus Involve Scientists from the Institute of Biophysics in Moscow, Russian Federation

after Brooks 7-14-95

4. Kisselev - January start
- Florida conformation - milestones
- time & participants needs alot of financial support
- Institute can't make funding even at start point
- start of this project only take place only after real funding support from U.S. side
- approves it: real importance but no money
- Mayak Complex also takes part in this project (minatom report ?)

- maybe some stages could start in Mayak Facility!

- Delay to JCCRER sitting in Moscow?

- when will Mikhail have intended funding to start this:
- large part of project deals with Mayak Complex
- able to provide support funds to Mayak Facility to start?
- can start coordination as first item
- Dr. Okuniewska-?

- Funding from U.S. side: have to provide funds to U.S participants in this
in addition provide partial support to R.F. scientists
- have made report: not be possible to spend money without agreement and approval of project
- new mechanism to provide support to Mayak to

Kiselev will give final answer after discussing this

Ilyina
Unless EC gives approval; nothing can start; waste of time
hard work of scientists, if delayed, may impact derive and
cause damage

- Shalnov: [illegible] approve it: and discuss financing

- Mayak hasn't agreed to participate

Alex / - to start this project at this time; too early
- funding on R.E. side not confirmed in official manner
- a solve participants of Mayak in this project (very hard financial situation)
no state budget for Mayak Complex

- Does you have a means to provide future funding for
Mayak Complex to start this -

- EMERCOM - starting from January can put it into contract
EMERCOM regularity declined since last time

- include at next meeting = accept it scientifically
but ask U.S. to find funding for this work

- recommend Bolchov not to sign at this time; not proper to sign
until each side has committed financial support

- why 2.3 greater problems and 2.1 & 2.2 doesn't -
The dosimetric database is common for all 3 projects

Kirtelov 2.1-2.2 – based on data approved and in her database

Stochastic – historically data of radiation safety are

– large amount of work with many ok complex

Lubov – wait for right temper to resolve this –
wait until very accurate & accurate to go in this direction

discrepancy in text of this ~~text~~ project

– put away this discrepancy in text = partial support needed

– protocol of today meeting: agree to technical part EC approve it

– order to check to re-work ~~3 questions~~ on financial questions

– H.P. won't sign until financial question resolved

HP – needs to know funding level available before can partial support

Lubov – when we get U.S. proposed amount: EMERCOM will provide equivalent amount

Gubov –

HP what are the total costs to perform research from R.F. side = how much EMERCOM to add – subtract of U.S. side needed

– reverse process = ~~total~~ amount then leads to proposal

– Nikolai why can't a determination be made on the costs of the personnel as written.

– Needs serious consideration: if too many funds necessary for either side to support, then we

ask R.F. EC reps during next 2 weeks to give
estimate of amount of funds necessary

- U.S. side should give attitude
  R.F. side supported well research
  U.S side can support U.S research.

- What are costs to carry out project:
  cooperative

- stop transition now: what are costs of equipment, materials, and travel

- in today's meeting: ask Co-chairs to give as soon as we solve financial & organizational problem

~~side bar~~ typo on 2.3

- statement on technical merits of work
- need not 60 days Co-chairs make this one
- Co-chairs will give after needing financial issue

5 Direction 3

Project 3.2 protocol

- started in Feb '95 - full collaborative experience
- H.P will mention Budget
- 3.2 A -
  ☑ not received list of Russian experts - he has (passed out)
  - all will mention - (< 14 persons)

3.2 B - Exercise (simulation) to test manual

- not to exceed 20% support to anybody

AP Technical aspects & time frames outlined are acceptable?

- final volume of work determined by
- will be a useful document : don't be frightened by large bk of documents we will work with

proceed as same lines as 2,3

- jointly approved all technical aspects & technical specs in meeting next

- for budgetary - individual assume responsibility of countries on each ccc
  - U.S. would take care of U.S. workshops
  - determine assistance needed on RAE workshops from U.S. side

- This figures: (amounts / estimates of various workshops in U.S. (total costs)

- Henry : attempt to keep workshops small & manageable
  - no Ainsworth, Henry, Parker
  - no identification of resources, logistics,
  - concerned with 3.2 B particularly
  - initial funds estimate related with 3.2 A

- GCC inter-agency coordination is reviewed
  - good political : (Health Committee - Energy Committee)
  - 2 EC members already on this project [should not be submitted to IRG] (hidden members)
  - keep project practical, small, reasonable amounts - with

- Russian Who is to be the authorities for this?

3.2B?

at Min of Health special medical that deals with energy actuators

may be some of these participate [Ainsworth - Heinz - Pavlova - Paulo Filho]

6 New Projects

- Agreement on real procedure for consideration.
  - not actual proposals
- How to coordinate a step by step process for system: keep open to new projects
- Important to have some administrative procedure to follow.
  This year will probably be different than next year
  (U.S. doesn't have SRG for this year)
  - Eventually SRG will handle these projects
  - work together on this
  - after inaugural SRG - create an mechanism for both SRG's to operate cooperatively
  - JCCHER will want to see concerns from SRG for them
- what can we & can't we do to handle & process these proposals we get (U.S. - R.F. both getting them)
- each side has system for evaluating unsolicited proposals (& solicited)
  - EH-6 re-evaluating our whole review process
  - a document a process for handling them
- HP will report back on the outcome of this

First year, research will (EC) important job to act
- as conscience of peer-review group - quality of work - hours
adjust priorities

Kiseley 2nd workshop - 4 additional projects & priorities established
to presentation to EC; how to react to these 4 proposals:
- pass on to JCCRER or forget about it
- they do reflect scientific experts at workshop

HP. scientists did a reasonable job of lining up the priorities
- don't know if the 4 reflect JCCRER priorities.)

- EC in position to understand financial constraints -
able to evaluate when & how to handle them
- JCCRER expects EC to perform selection & presentation.

Henry - watchdog and an outlet of Thyroid cancer in Belarus -
- when & when to you announce award of joint funds
- won't accept papers that don't have full publication information
public announcement
- when to make this (year - 2 years)
- joint SET models (Europe - Chile)

=== need sense of resources available (max) first
not before Oct (JCCRER) only after that
if SRG: work out mechanism to handle them

Leonid open to setting up rules of some necessary

СОТРУДНИЧЕСТВО В ОБЛАСТИ ИЗУЧЕНИЯ РАДИАЦИОННЫХ ВОЗДЕЙСТВИЙ

COOPERATION IN RESEARCH ON RADIATION EFFECTS

Section 3 important to give EC a sense of what
- scientists are jointly studying

- not a high increase next year expected (w/ to Galson amount)
  - only pilot studies
  - increase of projects not expected

- work according to practical, concrete steps, guiding different agencies -
  how to combine to make some realistic projects

- Important that Tsyb (working as leader of 7 of JCCNRS) presented his proposal under JCCRER

HP - you don't have a process or procedure
  - Section 3 items: pass on to SRG when ready
  - 2.3 & 3.2 along lines of EC responsibility under JCCRER

- Section 3 - already supported under JCCCNRS = already a mechanism WGF

- DOE '96 - no different from DOE '95 (EH-63) funding level
  . difficult to promote new projects: Chernobyl may have a resonance (Tho positive)

Luhov - have support by Russian side: will be supported independently by R.F.

- if U.S. scientists has interest in Altai due research - OK
  from R.F. side no funding

- EMERCOM intends to support some activities in Altai.

lunch

after lunch

- how to optimize approaches & will ask us results of our discussions
- what are our proposals?
- those that do have other support evidence available now & to be available in the future
- could be additional fiscal support in next fiscal year?
- Can we give to JCCRER reports to be developed in the next year of work?

HP JCCRER wouldn't want to give support to a study if without financial support to carry it out effectively
— P. Heinz

- how to proceed on 2.3 & 3.2 first: before considering others (HP)
- (Smith -) priorities very important
- if funding for #3 or 4, what about #1 first
- EC decides another different priorities than the scientists decide
- must be flexible on over financial support
- efficient(first) basis 2.3 & 3.2 first: JCCRER gave EC responsibility to implement
- as second consideration on those scientific priorities of this workshop
- Then pre-existing funding be considered as a basis to provide even though not #1 priority from workshop priorities
- wants to delay decision/approval of priorities from sections 3

- have to JCCRER to make recommendations on these priorities from the workshop

- considerations shared at wkshp.
  - noted a number of criteria were to explore
- intention to take this & others we have to refer to SRG to review in entirety - then there recommendations forwarded to JCCRER for final approval

- P. Henry (trouble without any rules of the game)
  - note record of meeting of these
  - this is what these participants said
  - refrain from saying open to new proposals
  - are you ready to receive proposals? Do you have money? N. No for them
  - let the scientists know if they come in a precursor
  - Terms of Research guidelines: submit to EC in accordance with guidelines.
    SRG to review & recommend these participants are to JCCRER to make final proposal
  - case page: log it in: track it and its outcome
    site ita # / research
  - balance the expectation of PRT of what a budget is appropriate if funds is available

- already written into guidelines
- Leonid

- next JCCRER: can we submit new ones?

- What is aspect of new ~~appeal~~ proposal from Moscow this last year? (Leonid)

- (HP) - EC given charge for first year:
now! The time to transfer to SRG

- what received, in process, to policy council?

- If open for business: make declaration public: make it clear English/Russian, conform to guidelines, logged in, get back to JCCRER

- message to JCCRER; we are open for business, run an open and transparent system - can respond with SRG evaluation

- very limited money available
- Then may re-submit -

- Stopping step at EC level - (This possible before JCCRER)
- Procedures for SRG too: (This not possible before JCCRER)

Leonid: For next JCCRER let co-chair organize the work for consider & approval that meet guidelines for JCCRER

- one year mandate: if JCCRER can expand to 1 or 2 more consider to EC

make EC before JCCRER meets: ~~if not~~ much easier to do -

(HP) - caveat on JCCCNRS chemical study

7. Financial - rather close to solution of real transfer of US funds to R.F. institutes

Direct funding of facilities: being worked on

- solution seems to be realistic
- MOA draft is acceptable = Vozniak final signature within a week
- pivotal document to allow DOE to transfer funds
- alot of angst at scientific level

- DOE has met the Oct. '94 funding level = assume that equivalent level met by EMERCOM
- be able to report to policy council resolved (~3 weeks based on our experience with workshop transfer)
- financial portfolio should be coordinated: re-view the $1 million committed in last JCCRER
- real work only started ½ year - U.S. $1.2 million total DOE

Shlomo MOA = why sticking points? — copy to Shlomo for latest version of MOA

Shlomo comments to Shlomo

??

8. Range of dates to send to JCCRER for policy-level dates -
last 10 days of October plus first week of November
{20th Oct ——— up to 5th November}
window for next JCCRER meeting.

- 1 day meeting of EC before & after JCCRER
- visit to Chelyabinsk also [reason to organize after this meeting]

Shlomo, visit ~~wife~~ useful before JCCRER: more informed JCCRER

- accompany of delegates to Chelyabinsk also EC meeting
- EC after JCCRER
- coordinate; whether before or after JCCRER visit to Urals
- EC → JCCRER → visit Then back for EC meeting.

small meeting